

REMARKS

Claims 1-65 are pending. Claims 9, 14, 21, 27, 38, 47, and 54-65 are withdrawn from consideration. Claims 1, 3, 17, 18, 26, 29, 34, 40, 44, and 48 have been amended. Claims 2, 4, 5, 28, 39, and 41 have been canceled. No new matter has been added as a result of the amendments.

Objection – Minor Informalities

The title has been objected to for alleged excessive length.

As reflected in the Amendments to the Specification section of this response, above, Applicants request that the title be amended to read as follows: “Stabilized peptide formulations”.

Rejections under 35 U.S.C. § 112

The Office Action rejects claims 1-2, 4-8, 10, 17, 19-20, and 22-25 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. Specifically, the Action states that "The generic statements a stabilized peptide formulation comprising a peptide containing at least one histidine residue and at least one asparagines residue and functionally equivalent variants thereof of glucagons do not provide ample written description for the compounds since the claims do not describe a single structural feature. The specification does not clearly define or provide examples of what qualify as compounds of the claimed invention."

Claims 1 and 17 have been amended to specify that the peptide is PACAP 66 or a salt thereof. Support for such amendment resides, for example, in original claim 3 and on page 3, line 8 of the application as filed.

The Action further states that "...though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of derivatives."

The Action additionally states that "Description of PACAP 66 is not sufficient to encompass numerous other peptides that belong to the same genus, a peptide formulation comprising a peptide containing at least one histidine residue and a peptide containing at least one asparagines residue... There is not sufficient amount of examples provided to encompass the numerous characteristics of the whole genus claimed."

Finally, the Action states that "The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention... Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention."

All of the above-iterated objections are overcome by the amendment of claims 1 and 17. Claims 6-8, 10, 19-20, and 22-25 depend, either directly or indirectly from claims 1 and 17. Claims 2, 4, and 5 have been canceled. Accordingly, Applicants respectfully request that the present rejection of claims 1-2, 4-8, 10, 17, 19-20, and 22-25 under 35 U.S.C. § 112, first paragraph, be withdrawn.

Rejections under 35 U.S.C. § 102

Gockel

The Office Action rejects claims 1, 4, 6, and 7 under 35 U.S.C. §102(b) as being anticipated by Gockel, *et al* (hereinafter referred to as "Gockel"). Applicants respectfully disagree.

As mentioned above, claim 1 has been amended to specify that the peptide is PACAP 66 or a salt thereof.

Gockel does not recite the peptide formulation of amended claim 1. Rather, Gockel teaches a cyclic dipeptide selected from the group consisting of c-HisHis, c-GlyCys, c-HisCys, and c-CysCys in a zinc nitrate solution. To form the basis of a proper rejection under 35 U.S.C. § 102(b), a cited reference must disclose each and every element of the rejected claim(s). *See Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Gockel does not

disclose a stabilized peptide formulation comprising the peptide PACAP 66 or a salt thereof. Thus, Gockel does not anticipate amended claim 1.

If an independent claim is not anticipated (i.e., is novel), then any claim depending therefrom is not anticipated. Claims 6 and 7 depend, either directly or indirectly, from claim 1. The novelty of claim 1 in view of Gockel having been established, it is likewise established for dependent claims 6 and 7.

Accordingly, Applicants respectfully request that the present rejection be withdrawn.

Krstenansky

The Office Action rejects claim 17 under 35 U.S.C. §102(b) as being anticipated by US 5,789,540 (hereinafter referred to as "Krstenansky"). Applicants respectfully disagree.

Krstenansky describes certain peptide derivatives. Claim 17 has been amended to specify that the peptide is PACAP66 or a salt thereof. Krstenansky neither describes PACAP66 nor a salt thereof. To form the basis of a proper rejection under 35 U.S.C. § 102(b), a cited reference must disclose each and every element of the rejected claim(s). *See Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Krstenansky fails to recite PACAP66 or a salt thereof and, thus, fails to anticipate amended claim 17.

Applicants respectfully request that the present rejection be withdrawn.

Kamei

The Office Action rejects claims 1-2 and 4-8 under 35 U.S.C. §102(b) as being anticipated by US 5,480,868 (hereinafter referred to as "Kamei"). Applicants respectfully disagree.

Kamei describes a sustained-release preparation comprising a physiologically active peptide of a general formula. As mentioned above, claim 1 of the instant application has been amended to specify that the peptide is PACAP 66 or a salt thereof. Kamei does not disclose a stabilized peptide formulation comprising the peptide PACAP 66 or a salt thereof. Thus, Kamei does not anticipate amended claim 1.

If an independent claim is not anticipated (i.e., is novel), then any claim depending therefrom is not anticipated. Claims 6-8 depend, either directly or indirectly, from claim 1.

Claims 2, 4, and 5 have been canceled. Claim 1 is novel in view of Kamei; accordingly, dependent claims 6-8 are novel, as well.

Applicants respectfully request that the present rejection be withdrawn.

Bouman

The Office Action rejects claims 1-2, 4-8, 34-36, 39, and 41-43 under 35 U.S.C. §102(b) as being anticipated by US 2,902,408 (hereinafter referred to as "Bouman"). Applicants respectfully disagree.

Claims 1 and 34 have been amended to specify that the peptide is PACAP 66 or a salt thereof.

To form the basis of a proper rejection under 35 U.S.C. § 102(b), a cited reference must disclose each and every element of the rejected claim(s). *See Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Bouman describes a process for preparation of long-acting suspensions of drugs. Bouman does not describe a stabilized peptide formulation comprising PACAP 66 or a salt thereof. Thus, Bouman anticipates neither amended claim 1 nor amended claim 34.

If an independent claim is not anticipated (i.e., is novel), then any claim depending therefrom is not anticipated. Claims 6-8 depend, either directly or indirectly, from claim 1. Claims 35-36 and 42-43 depend, either directly or indirectly, from claim 34. Claims 2, 4, 5, and 41 have been canceled. Amended claims 1 and 34 are not anticipated by Bouman; as a result, neither are claims 6-8, 35-36, and 42-43.

Applicants respectfully request that the present rejection be withdrawn.

Ohsaki

The Office Action rejects claims 44-46 and 50 under 35 U.S.C. §102(b) as being anticipated by US 5,428,129 (hereinafter referred to as "Ohsaki"). Applicants respectfully disagree.

Ohsaki is directed to the synthesis of cyclic peptides (preferably a synthetic calcitonin derivative).

To form the basis of a proper rejection under 35 U.S.C. § 102(b), a cited reference must disclose each and every element of the rejected claim(s). *See Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Claim 44 has been amended to specify that the peptide is PACAP 66 or a salt thereof. Ohsaki does not describe the preparation of a stabilized peptide formation comprising PACAP 66 or a salt thereof. Accordingly, Ohsaki does not anticipate amended claim 44.

If an independent claim is not anticipated (i.e., is novel), then any claim depending therefrom is not anticipated. Claims 45, 46, and 50 depend, either directly or indirectly, from claim 44. Because claim 44 is novel in view of Ohsaki, it follows that claims 45, 46, and 50 are novel in view of Ohsaki, as well.

Applicants respectfully request that the present rejection be withdrawn.

Pallenberg

The Office Action rejects claims 1, 6, 8, 10, and 34-37 under 35 U.S.C. §102(b) as being anticipated by US 5,538,945 (hereinafter referred to as "Pallenberg"). Applicants respectfully disagree.

Pallenberg discloses peptide-copper complexes for stimulating hair growth.

Claims 1 and 34 have been amended to specify that the peptide is PACAP 66 or a salt thereof. Pallenberg does not disclose a complex in which the peptide is PACAP 66 or a salt thereof. Thus, Pallenberg does not anticipate amended claim 1 or 34.

If an independent claim is not anticipated (i.e., is novel), then any claim depending therefrom is not anticipated. Claims 6, 8, and 10 depend, either directly or indirectly, from claim 1, and claims 35-37 depend, either directly or indirectly, from claim 34. The establishment of novelty of amended claims 1 and 34 results in the same for claims 6, 8, 10, and 35-37.

Applicants respectfully request that the present rejection be withdrawn.

Pan

The Office Action rejects claim 26 under 35 U.S.C. §102(b) as being anticipated by WO 01/23420 A2 (hereinafter referred to as "Pan"). Applicants respectfully disagree.

Pan describes peptides that stimulate insulin release from pancreatic beta cells in a glucose-dependent manner.

The Examiner directs Applicants' attention to Example 5 ("Peptide Synthesis Methodology"). According to the Examiner, "The precipitate was washed three times with the cold ether and then dissolved in 5% acetic acid prior to lyophilization (Example 5)."

To form the basis of a proper rejection under 35 U.S.C. § 102(b), a cited reference must disclose each and every element of the rejected claim(s). *See Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Claim 26 has been amended to specify that the acid is inorganic. Pan does not describe a stabilized peptide formulation comprising a dried mixture of an inorganic acid and PACAP 66 or a salt thereof. Thus, Pan does not anticipate amended claim 26.

Applicants respectfully request that the present rejection be withdrawn.

CONCLUSION

In view of the amendments and arguments presented above, Applicants believe the pending application is in condition for allowance. Should the Examiner believe that a telephone conversation with Applicants' attorney/agent would expedite prosecution of this application, she is cordially invited to call the undersigned attorney/agent. Please charge any required fee or credit any overpayment to Deposit Account No. 04-1105.

Dated:

Respectfully submitted,

By 

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